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EXAMINER	
CHEN, SHIN LIN	
ART UNIT	PAPER NUMBER
1632	

NOTIFICATION DATE	DELIVERY MODE
06/25/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/594,595	KATO ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5-4-09 & 5-14-09*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *8-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9-28-06, 9-28-07, 11-20-07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group I, claims 1-7, in the reply filed on 5-4-09 and 5-14-09 is acknowledged. The traversal is on the ground(s) that groups I and II are closely related, searching one group would need to search another group, therefore, there is no undue burden to search both groups. The reference cited by Examiner does not teach each and every element of the claimed invention, so the reference does not serve to destroy the lack of unity of the claimed invention. This is not found persuasive because a search for the agent that enhances the migration and accumulation of mesenchymal stem cells does not require a search for using the agent for regeneration therapy of injured tissue. The search would not be coextensive. The putative special technical feature common to groups I and II is the agent or transplant for enhancing the migration or accumulation of mesenchymal stem cells. Fiedler et al., 2002 (Journal of Cellular Biochemistry, Vol. 87, p. 305-312) discloses that human platelet derived growth factor bb (rhPDGF-bb) can stimulate migration of primary human mesenchymal progenitor cells (MPC) in a dose-dependent manner. Therefore, there is no special technical feature contributed by the instant invention over the prior art. The element of claim 1 is the agent that enhances the migration and accumulation of mesenchymal stem cells and Fiedler does teach every element of claim 1.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 8-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 5-14-09.

Applicants' amendment filed 9-28-06 has been entered. Claims 1-15 have been amended. Claim 16 has been canceled. Claims 1-15 are pending. Claims 1-7 are under consideration.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Double Patenting

4. Applicant is advised that should claim 1 be found allowable, claim 2 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 2 still reads on the agent or transplant, the intended administration mode does not change the content of the agent or transplant and is irrelevant to the agent or transplant of claim 1.

5. Applicant is advised that should claim 1 be found allowable, claim 3 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The agent or transplant itself is a mesenchymal stem cell migration-enhancing factor.

6. Applicant is advised that should claim 1 be found allowable, claim 5 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 5 still reads on the agent or transplant, the intended use in regeneration therapy does not change the content of the agent or transplant and is irrelevant to the agent or transplant of claim 1.

7. Applicant is advised that should claim 1 be found allowable, claim 6 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 6 still reads on the agent or transplant, the intended use in regeneration therapy does not change the content of the agent or transplant and is irrelevant to the agent or transplant of claim 1.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "and/or" in line 2 of claim 1 is vague and renders the claim indefinite. It is unclear what is intended "and" or "or" or both. Changing the term "and/or" to "...or... or both" would be remedial. Claims 2-7 depend from claim 1.

The phrase "the agent or transplant according to claim 1, administering simultaneously with, or continuously to, or separately from mesenchymal stem cells" in claim 2 is vague and renders the claim indefinite. It is unclear what is administered simultaneously with, what is administered continuously and to where it is administered, and what is separately from mesenchymal cells. Claim 2-7 depend from claim 1.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims read on any nucleic acid molecule, protein, peptide, antibody, small organic compound, cell or tissue that can enhance the migration and accumulation of mesenchymal stem cells in an injured tissue. The specification discloses that PDGF-BB, bFGF, HB-EGF, TGF-

alpha, PDGF-AB, IGF-I, EGF, alpha-thrombin and HGF can enhance the migration and proliferation of the rabbit-derived mesenchymal stem cells (e.g. Examples 2-3).

The claims encompass various nucleic acid molecules, proteins, peptides, antibodies, small organic compounds, and cells and tissues that can enhance the migration and accumulation of mesenchymal stem cells in an injured tissue, and they are highly variant from each other and a significant number of structural differences between them are permitted. The specification fails to provide the structural features of the various nucleic acid molecules, proteins, peptides, antibodies, small organic compounds, cells and tissues. Structural features that contribute to the enhancement of the migration and accumulation or suppression of diffusion of the administered mesenchymal stem cells in an injured tissue have not been disclosed. No common structural attributes identify those various nucleic acid molecules, proteins, peptides, antibodies, small organic compounds, and cells and tissues. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe common attributes or characteristics that identify those nucleic acid molecules, proteins, peptides, antibodies, small organic compounds, cells and tissues and they are highly variant, the disclosed PDGF-BB, bFGF, HB-EGF, TGF-alpha, PDGF-AB, IGF-I, EGF, alpha-thrombin and HGF in the present application are insufficient to describe the full scope of various nucleic acid molecules, proteins, peptides, antibodies, small organic compounds, and cells and tissues encompassed by the claims.

This limited information is not sufficient to reasonably convey to one skilled in the art that applicants were in possession of the claimed agents and transplants. Thus, it is concluded

that the written description requirement is not satisfied for the claimed agents and transplants that can enhance the migration and accumulation of mesenchymal stem cells in an injured tissue.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

With the exception of the molecules referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed nucleic acid molecule, and therefore conception is not achieve regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only the disclosed molecules, but not the full breadth of the claim meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-*

Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

12. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the PDGF-bb, HB-EGF, TNG-alpha, FGF-2 and HA as discussed in the references cited below under 35 U.S.C. 102 rejection and IGF-I, alpha-thrombin and HGF as disclosed in the specification, does not reasonably provide enablement for various agents or transplants for enhancing the migration and accumulation of administered mesenchymal stem cells in an injured tissue. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

While determining whether a specification is enabling, one considered whether the claimed invention provides sufficient guidance to make and use the claimed invention, if not, whether an artisan would have required undue experimentation to make and use the claimed invention and whether working examples have been provided. When determining whether a specification meets the enablement requirement, some of the factors that need to be analyzed are: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and whether the quantity of any necessary experimentation to make or use the invention based on the content of the disclosure is "undue" (In re Wands, 858 F.2d at 737, 8 USPQ2d 1400, 1404 (Fed. Cir.1988)).

Furthermore, the USPTO does not have laboratory facilities to test if an invention with function as claimed when working examples are not disclosed in the specification, therefore, enablement issues are raises and discussed based on the state of knowledge pertinent to an art at the time of the invention, therefore skepticism raised in the enablement rejections are those raised in the art by artisans of expertise.

The claims are directed to an agent or a transplant for enhancing the migration and accumulation of administered mesenchymal stem cells in an injured tissue or suppressing the diffusion of administered mesenchymal stem cells from an injured tissue. Claim 2 specifies administering simultaneously with, or continuously to, or separately from mesenchymal stem cells. Claim 3 specifies the agent or transplant contains a mesenchymal stem cell migration-enhancing factor. Claim 4 specifies the mesenchymal stem cell migration-enhancing factor enhances the proliferation or mesenchymal stem cells. Claims 5 and 6 specify the agent or transplant is used in regeneration therapy of recited injured tissues.

The claims encompass various nucleic acid molecules, proteins, peptides, antibodies, small organic compounds, and cells and tissues that can enhance the migration and accumulation of mesenchymal stem cells in an injured tissue. The specification discloses that PDGF-BB, bFGF, HB-EGF, TGF-alpha, PDGF-AB, IGF-I, EGF, alpha-thrombin and HGF can enhance the migration and proliferation of the rabbit-derived mesenchymal stem cells (e.g. Examples 2-3).

As discussed above, the specification fails to provide the structural features of various nucleic acid molecules, proteins, peptides, antibodies, small organic compounds, cells and tissues that contribute to the enhancement of the migration and accumulation or suppression of diffusion of the administered mesenchymal stem cells in an injured tissue. Applicants apparently do NOT

have possession of those various nucleic acid molecules, proteins, peptides, antibodies, small organic compounds, and cells and tissues that can enhance the migration and accumulation of mesenchymal stem cells in an injured tissue other than those proteins disclosed in the instant invention. Therefore, it is not enabled to use the claimed agent and transplants to enhance the migration and accumulation of mesenchymal stem cells in an injured tissue without possession of those agents and transplants. Absent specific guidance, one skilled in the art at the time of the invention would not know how to use the claimed agents or transplants to enhance the migration and accumulation of mesenchymal stem cells in an injured tissue. Thus, one skilled in the art at the time of the invention would require undue experimentation to practice over the full scope of the invention claimed. This is particularly true based upon the nature of the claimed invention, the state of the art, the unpredictability found in the art, the teaching and working examples provided, the level of skill which is high, the amount of experimentation required, and the breadth of the claims.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. Claims 1-3 and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Fiedler et al., 2002 (Journal of Cellular Biochemistry, Vol. 87, p. 305-312).

The claims are directed to an agent or a transplant for enhancing the migration and accumulation of administered mesenchymal stem cells in an injured tissue or suppressing the diffusion of administered mesenchymal stem cells from an injured tissue. Claim 2 specifies administering simultaneously with, or continuously to, or separately from mesenchymal stem cells. Claim 3 specifies the agent or transplant contains a mesenchymal stem cell migration-enhancing factor. Claims 5 and 6 specify the agent or transplant is used in regeneration therapy of recited injured tissues. Claim 7 recites the mesenchymal stem cell migration-enhancing factor.

Fiedler discloses that human platelet derived growth factor bb (rhPDGF-bb) can stimulate migration of primary human mesenchymal progenitor cells (MPC) in a dose-dependent manner. The effect of rhPDGF-bb as chemoattractive proteins for primary human MPC suggests a functional role for recruitment of MPCs during bone development and remodeling, as well as fracture healing (e.g. abstract). The mesenchymal progenitor cell is a type of mesenchyma stem cell. The claims are product claims that the intended use of the agent or transplant does not carry weight in 35 U.S.C. 102(b) rejection. Thus, the claims are anticipated by Fiedler.

15. Claims 1-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Gerber et al., 2002 (US 20020132978 A1).

The claims are directed to an agent or a transplant for enhancing the migration and accumulation of administered mesenchymal stem cells in an injured tissue or suppressing the

diffusion of administered mesenchymal stem cells from an injured tissue. Claim 2 specifies administering simultaneously with, or continuously to, or separately from mesenchymal stem cells. Claim 3 specifies the agent or transplant contains a mesenchymal stem cell migration-enhancing factor. Claim 4 specifies the mesenchymal stem cell migration-enhancing factor enhances the proliferation or mesenchymal stem cells. Claims 5 and 6 specify the agent or transplant is used in regeneration therapy of recited injured tissues. Claim 7 recites the mesenchymal stem cell migration-enhancing factor.

Gerber teaches that the growth factor HB-EGF stimulates mesenchymal cell proliferation and migration and promotes renal epithelial cell survival (e.g. [0055]). The mesenchymal cell is "an undifferentiated cell found in mesenchyme and capable of differentiating into various specialized connective tissues" (Answers.com, mesenchymal cell). A mesenchymal cell is also a mesenchymal stem cell. The claims are product claims that the intended use of the agent or transplant does not carry weight in 35 U.S.C. 102(e) rejection. Thus, the claims are anticipated by Gerber.

16. Claims 1-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Gingras et al., 2002 (US 20020128444 A1).

The claims are directed to an agent or a transplant for enhancing the migration and accumulation of administered mesenchymal stem cells in an injured tissue or suppressing the diffusion of administered mesenchymal stem cells from an injured tissue. Claim 2 specifies administering simultaneously with, or continuously to, or separately from mesenchymal stem cells. Claim 3 specifies the agent or transplant contains a mesenchymal stem cell migration-

enhancing factor. Claim 4 specifies the mesenchymal stem cell migration-enhancing factor enhances the proliferation or mesenchymal stem cells. Claims 5 and 6 specify the agent or transplant is used in regeneration therapy of recited injured tissues. Claim 7 recites the mesenchymal stem cell migration-enhancing factor.

Gingras teaches that cytokines interleukin-1 (IL-1) and tumor necrosis factor-alpha (TNF-alpha) stimulate vascular invasion of the injured tissue and migration and proliferation of the mesenchymal cells that start the repair process (e.g. [0005]). The mesenchymal cell is "an undifferentiated cell found in mesenchyme and capable of differentiating into various specialized connective tissues" (Answers.com, mesenchymal cell). A mesenchymal cell is also a mesenchymal stem cell. The claims are product claims that the intended use of the agent or transplant does not carry weight in 35 U.S.C. 102(e) rejection. Thus, the claims are anticipated by Gingras.

17. Claims 1-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Badylak et al., 2002 (US Patent No. 6,375,989 B1).

The claims are directed to an agent or a transplant for enhancing the migration and accumulation of administered mesenchymal stem cells in an injured tissue or suppressing the diffusion of administered mesenchymal stem cells from an injured tissue. Claim 2 specifies administering simultaneously with, or continuously to, or separately from mesenchymal stem cells. Claim 3 specifies the agent or transplant contains a mesenchymal stem cell migration-enhancing factor. Claim 4 specifies the mesenchymal stem cell migration-enhancing factor enhances the proliferation or mesenchymal stem cells. Claims 5 and 6 specify the agent or

transplant is used in regeneration therapy of recited injured tissues. Claim 7 recites the mesenchymal stem cell migration-enhancing factor.

Badylak teaches growth factors FGF-2 and TGF-beta have been identified as particularly important to wound healing and tissue remodeling. FGF-2 promotes mesenchymal cell migration and proliferation to accelerate healing of gastric mucosa and calvarian bone (e.g. bridging columns 15 and 16). The mesenchymal cell is "an undifferentiated cell found in mesenchyme and capable of differentiating into various specialized connective tissues" (Answers.com, mesenchymal cell). A mesenchymal cell is also a mesenchymal stem cell. The claims are product claims that the intended use of the agent or transplant does not carry weight in 35 U.S.C. 102(e) rejection. Thus, the claims are anticipated by Badylak.

18. Claims 1-3 and 5-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Desnoyers et al., 2008 (US Patent No. 7,456,262 B2).

The claims are directed to an agent or a transplant for enhancing the migration and accumulation of administered mesenchymal stem cells in an injured tissue or suppressing the diffusion of administered mesenchymal stem cells from an injured tissue. Claim 2 specifies administering simultaneously with, or continuously to, or separately from mesenchymal stem cells. Claim 3 specifies the agent or transplant contains a mesenchymal stem cell migration-enhancing factor. Claims 5 and 6 specify the agent or transplant is used in regeneration therapy of recited injured tissues. Claim 7 recites the mesenchymal stem cell migration-enhancing factor.

Desnoyers teaches that hyaluronic acid (HA) is a component of skin and mesenchymal tissue where it facilitates cell migration during wound healing (e.g. bridging columns 3 and 4). The mesenchymal cell is "an undifferentiated cell found in mesenchyme and capable of differentiating into various specialized connective tissues" (Answers.com, mesenchymal cell). A mesenchymal cell is also a mesenchymal stem cell. The claims are product claims that the intended use of the agent or transplant does not carry weight in 35 U.S.C. 102(e) rejection. Thus, the claims are anticipated by Desnoyers.

Information Disclosure Statement

19. The references cited in the information disclosure statement filed 9-28-06 are duplicates of the references cited in the information disclosure statement filed 9-28-07. Further, the references cited in the information disclosure statement filed 11-20-07 are duplicates of the references cited in the information disclosure statement filed 9-28-07. Therefore, the information disclosure statements filed 9-28-06 and 11-20-07 will not be considered. It has been placed in the application file, but the information referred to therein has not been considered as to the merits.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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